REMARKS

Claims 1-13 remain pending in the present application.

Rejection under 35 U.S.C. 103 over Adachi et al. in view of Sheffield et al.

Claims 1-13 are rejected under 35 U.S.C. §103(a) as obvious over Adachi et al. in view of Sheffield et al. Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

Adachi et al. is discussed at length in the present specification at page 5, lines 6-26 (identified as "Shinya et al."), wherein Applicants indicate that the authors administered Tranilast orally both pre- and post-operatively in a rat intraperitoneal adhesion model.

Adachi et al. fail to disclose or suggest "...locally administering a composition comprising a delivery vehicle containing Tranilast, or an analog thereof, directly onto said tissue surfaces at the surgical site..." as is required by claim 1.

The Examiner cites Adachi et al. for the proposition that

> Adachi describes how to prevent postoperative intraperitoneal adhesions by oral administration of composition comprising tranilast and carboxymethylcellulose prior to and after surgery (see the whole document with emphasis on the abstract and page 52). The carboxymethylcellulose meets the limitation of delivery vehicle of claim 1. Therapeutically effective amount as recited in claim 1 is any amount deemed effective by the artisan. Administration of 60 mg/kg per day represents a single dose as recited in claim 8 and also meets the limitation of claim 11. The carboxymethyl cellulose is a sustained release excipient so that the

> composition administered is in sustained release form meeting claims 9 and 10. The oral administration of tranilast composition prior to surgery meets the limitations of systemic administration and thus meets claims 12 and 13. The melted tranilast and the carboxy-methylcellulose are in solution form so that the carrier composition in claim 3 is met. (Office Action of June 8, 2009; page 3).

The Examiner recognizes that Adachi et al. fail to disclose or suggest local administration of Tranilast directly onto tissue surfaces at sites subject to adhesion formation.

> Adachi does not teach that the composition comprising tranilast is locally administered to tissue at surgical sites to treat adhesions. But, local and/or topical administration of therapeutic agents at surgical sites to treat or inhibit adhesion formation is known for various agents. (Office Action of June 8, 2009; pages 3-4).

The Examiner attempts to cure the deficiencies of Adachi et al. by citation of Sheffield et al., which discloses local administration of NSAID compounds to treat adhesions.

> Sheffield discloses method of inhibiting the formation of post surgical adhesion by administration of compositions to the site of surgical trauma to inhibit the post surgical adhesion (abstract; column 2, lines 34-38; column 3, lines 15-28, 39-56). The composition locally or topically administered at the surgical site comprises non-steroidal anti-inflammatory drug (NSAID) and pharmaceutically acceptable carrier (column 4, lines 12-29); when the composition is carried in a liposome or when the NSAID is encapsulated in a microcapsule, the composition of Sheffield meets the requirements of claim 3; when the polymeric carriers is lactide, the composition of Sheffield meets the requirements of claim 4. Furthermore, Sheffield teaches that the composition can be applied by catheterization using implanted osmotic pump (column 3, lines 29-38) so that when the delivery method is by osmotic pump, the requirement of claim 3 is met. (Office Action of June 8, 2009; page 4).

In formulating the reason for combining Adachi et al. and Sheffield et al., the Examiner concludes:

> Therefore, taking the teachings of Adachi and Sheffield, one having ordinary skill in the art at the time the invention was made would have reasonably expectation of success that topical or oral administration anti-adhesion composition of Adachi or Sheffield or the combined composition of Adachi and Sheffield would produce the expected inhibition of post surgical adhesion. (Office Action of June 8, 2009; page 4; emphasis added).

Applicants respectfully traverse the Examiner's conclusion that there would have been a reasonable expectation of success that a pharmaceutical compound known to be useful in oral administration (i.e. Tranilast) would be likewise useful for topical/local administration directly onto damaged tissue.

As discussed previously, Sheffield et al. is directed strictly to topical administration of NSAIDS for adhesion prevention. NDSAIDS are a completely different class of pharmaceuticals as compared to Tranilast, with completely different biological activities as compared to Tranilast. As such, one skilled in the art would not consider Tranilast a substitute for NSAIDS, whether administered orally or topically.

Further, the Examiner's proposal that because a particular pharmaceutical is known to have a particular efficacy through oral administration, that it would necessarily have similar efficacy if administered topically is scientifically questionable at best. Notably, even Sheffield et al. recognize the fallacy of such reasoning, as applied to corticosteroids:

> Corticosteroids have been administered intraperitoneally as well as systemically in efforts to prevent adhesions. (See the Stangel et al. article, cited above, on page 147, as well as the

> articles cited therein.) Some studies have questioned the efficacy of corticosteroids in adhesion prevention. In high doses, these materials may suppress the immune system and interfere with wound healing. Therefore, the use of corticosteroids does not seem to be an acceptable solution to the post-operative adhesion problem. (Sheffield et al., col. 1, lines 48-56; emphasis added).

Thus, the skilled artisan would not have been led to expect that every pharmaceutical, known to have efficacy when administered orally, would be efficacious if administered topically.

As the Examiner is well-aware, oral administration routes the pharmaceutical through the alimentary system, wherein it is acted upon by multiple body chemistries which often result in modification of the original pharmaceutical compound into various derivatives and/or reaction products, which are the efficacious compounds. If administered topically, there is no guarantee that similar chemistries will occur, and therefore topical efficacy cannot be certain, or even reasonably expected.

Accordingly, the skilled artisan would have had no reasonable expectation of success in inhibiting adhesions via topical application of Tranilast, derivable from the cited references. Withdrawal of the rejection is requested on this basis alone.

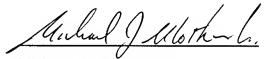
The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 50-2478 (14924).

In view of the foregoing, it is respectfully submitted that the present claims are in condition for allowance. Prompt notification of allowance is respectfully requested.

If the Examiner has any questions or wishes to discuss this application, the Examiner is invited to contact the undersigned representative at the number set forth below.

Respectfully submitted,

Date: August 14, 2009



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